



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/049,865	03/27/1998	COLLIN J. WEBER	47765/C/JPW/	6162

7590 12/16/2004

Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

DAVIS, MINH TAM B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/049,865

Applicant(s)

WEBER ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-59 and 62-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-59, 62-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1642

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 54-59, 62-70 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 54-59, 62-69 pertaining to while being enabled for a method for transplanting a viable xenogeneic cell or tissue, using CTLA4 or CTLA4Ig and microencapsulation of the cell or tissue, but not enabled for a method for transplanting a viable xenogeneic cell or tissue, using "a proteinaceous construct" that inhibits an immune system costimulation event and microencapsulation of the cell or tissue, remains for reasons already of record in paper of remains for reasons already of record in paper of 06/24/04.

Applicant argues that the claim 54 has been amended to replace "agent" with "a proteinaceous construct", and that the Examiner has conceded that the present application enables a method for transplanting a viable xenogeneic cell or tissue, using CTLA4 or CTLA4Ig (examples of proteinaceous constructs) and microencapsulation of the cell or tissue

Applicant's arguments set forth in paper of 09/27/04 have been considered but are not deemed to be persuasive for the following reasons:

Art Unit: 1642

It is noted that in view of a lack of definition of "a proteinaceous construct" that inhibits an immune system costimulation event and microencapsulation of the cell or tissue, "a proteinaceous construct" encompasses any protein inhibitors of an immune system costimulation event, having any structure, wherein the structure of which inhibitors is not necessarily the same as that of CTLA4 or CTLA4Ig. The specification however does not teach a common structure or consensus sequence for the claimed inhibitors. Therefore, one would not know how to make the claimed protein inhibitors for use in the claimed method, and given the unpredictability of the structure of the inhibitors used in the claimed method, it would be undue experimentation to screen the inhibitors for use in the claimed method.

REJECTION UNDER 35 USC 103

Claims 54-59, 62-70 remain rejected under 35 USC 103, pertaining to obviousness over Lenschow et al, in view of Goosen et al, Soon-Shiong et al, Akalin et al, Linsley et al, Padrid et al, and Steurer et al for reasons already of record in paper of 06/24/04.

Applicant argues that there is no motivation to combine the references and there is no reasonable expectation of success. Applicant further argues the unexpected synergistic effect of the claimed invention, i.e. improving graft survival rate and duration in comparison with those obtained with each therapeutic modality separately.

Applicant recites Genovese et al, in which a combination therapy provides no treatment benefit.

Art Unit: 1642

The recitation of Genovese et al is acknowledged and entered.

Applicant's arguments set forth in paper of 09/27/04 have been considered but are not deemed to be persuasive for the following reasons:

The motivation for combining the references is clear: Treatment by CTLA4Ig would complement encapsulation, because by directly preventing T cell recognition of the B7 antigen-presenting cells, CTLA4Ig not only reduces activation of T cells, thus reducing the number of host immune cells, but also induces long term donor-specific tolerance, which would be useful in organ transplantation, as taught by Lenschow et al.

Further, one would have been motivated to combine the teaching of Lenschow with Soon-Shiong and Goosen with a reasonable expectation of success, because CTLA4Ig treatment as taught by Lenschow et al, and encapsulation of islets taught by Soon-Shiong and Goosen are complementary to each other, i.e. reducing damaging by host immune cells to islets by different mechanisms, in addition to additional beneficial effect of long term donor-specific tolerance by CTLA4Ig alone, and prevention of penetration of large damaging molecules by encapsulation alone, and thus a combination of both treatment would enhance the chance of enhancing graft survival.

Moreover, concerning the unexpected results of the claimed method, Applicant argues limitation not the claims. The steps of the combined methods from the art are the same as the claimed method steps, and the cited results in the claims, i.e. inhibition the destruction of the transplanted cells or tissue are expected to be the same as the combined method taught by the art.

Art Unit: 1642

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

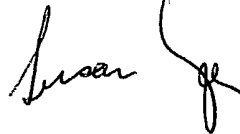
Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

December 07, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan', followed by a stylized flourish or initial.